

510(k) Summary of Safety and Effectiveness

Sysmex Corporation of America
Gilmer Road 6699 RFD
Long Grove, IL 60047-9596
(847)726-3662
Fax: (847)726-3505
Attention: Cathy Trester
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Sysmex™ SE/RAM-1, Trade name and Common name

The Sysmex™ SE/RAM-1 is substantially equivalent to the Sysmex™ SE-9000 (Premarket Notification K936023) and the R-3000 (Premarket Notification K912494). The Sysmex™ SE/RAM-1 is classified as a Class II device.

Intended Use

The SE/RAM-1 is an In Vitro device for whole blood cell analysis in clinical laboratories. The SE-9000 portion is intended for blood cell analysis; the RAM-1 portion is intended for automated reticulocyte analysis. The instrument is a screening device for identifying abnormal blood specimens. Medical technologists are responsible for final review of abnormal cells.

Device Description

The SE/RAM-1 is a table-top analyzer system consisting of a blood cell counting unit (SE-9000), a reticulocyte unit (RAM-1), a Data Management System, and a printer. A Sampler Unit is attached to the SE-9000 unit, which transports samples in cassette racks to the ID bar code reader and then to the Automatic mixing/Cap piercing device.

The SE/RAM-1 system has the capability of reporting up to 23 parameters. The 23 reportable parameters are as follows: RBC, Hgb, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, WBC, NEUT%, LYMPH%, MONO%, EO%, BASO%, NEUT#, LYMPH#, MONO#, EO#, BASO# (all from SE-9000 unit), RETIC %, RETIC# (from RAM-1 unit).

The SRV of the SE-9000 contains a port (in the original design of the instrument) by which the reticulocyte module (RAM-1) is attached. The SRV splits the blood sample into 8 aliquots. 7 aliquots are delivered to the SE-9000 system, diluted with the appropriate diluent or lyse and sent to their respective detector blocks for analysis. The 8th aliquot is sent to the RAM-1 where it is diluted and stained, then sent to the flow cell for analysis. The SE/RAM-1 system uses a total of up to 13 reagents. All reagents are the same as used on the stand-alone SE-9000 and the R-3000 analyzers.

Similarities and Differences of the SE/RAM-1 to SE-9000 and R-3000

Technology employed in the SE/RAM-1 system is exactly the same as is used in the SE-9000 and R-3000 analyzers. Differences are in software and minor tubing connections. All similarities and differences are described in Table 1.

Conclusion

In conclusion, the Sysmex™ SE/RAM-1 is a combination of the SE-9000 and R-3000 analyzers in one operating unit. The modifications of the instrument do not raise new issues of safety and effectiveness. The data presented shows the SE/RAM-1 to be substantially equivalent to the SE-9000 and R-3000.

**Table 1: Comparison of Sysmex™ SE/RAM-1 System to
Stand-alone SE-9000 and R-3000**

	SE-9000	SE/RAM-1 SE-9000 portion	R-3000	SE/RAM-1 RAM-1 portion
Intended use	In Vitro Device for CBC analysis	same	In Vitro Device for reticulocyte analysis	same
Sample type	EDTA anticoagulated whole blood	same	EDTA anticoagulated whole blood	same
Sample pathway	Open or closed mode, through SE-9000 SRV	same	Open or closed mode, through R- 3000 SRV	Open or closed mode, through SE-9000 SRV
Physical safety	See 510(k) #K936023	same	See 510(k) #K912494	same
Performance	#K936023	same	#K912494	same
Principles of Operation				
-Biosensor system	RF/DC	same	n/a	n/a
-Sheath flow	used in RBC/Plt counting	same	used in counting system	same
-Scattergram/histo- gram	See description	same	See description	Scattergram now in color; discriminator lines not displayed
-Fluorescence intensity	n/a	n/a	used in counting	same
-Forward scatter	n/a	n/a	used in counting	same
Physical hardware				
-Main unit	Hydraulic system Electronic system-PROM and PC based	same same	Hydraulic system Electronic system-PROM based	same Electronic system- PROM and PC based
-Power unit	power unit	same	n/a	n/a
-Laser power unit	n/a	n/a	LPU	same
-Pneumatic Unit	PU-1	same	same as SE	share PU with SE
-Sampler/barcode reader	10 rack sampler, LED	same	5 rack sampler, LED	Uses SE sampler/barcode reader
Software Programs			All R software is part of SE-DMS	
-Display	full color display	Same elements as SE-9000	monochrome display	Same elements as R- 3000 (now part of SE- DMS display)
-Stored Data	10000 sample storage	same	500 sample storage	10000(same as SE)
-QC program	15 files, 180 points/file	same	4 QC files, 60 points/file	12 files, 180 points/file
-QC material	SE-Check	same	Ret-Check	same
-Maintenance	See 510(k) #K936023	same	See 510(k) #K912494	see description and RAM-1 Ops manual, Chapter 5